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APPLICATION NO. 09/344,352	FILING DATE 06/23/99	FIRST NAMED INVENTOR SONN	ATTORNEY DOCKET NO. US0499/0101
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EXAMINER RUMED, D

ART UNIT 1647	PAPER NUMBER
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DATE MAILED: 01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/344,382

Applicant(s)

Soma et al.

Examiner
David Romeo

Group Art Unit
1647



☒ Responsive to communication(s) filed on 23 Oct 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 22-42 is/are pending in the application.

Of the above, claim(s) 29-42 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 22-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 22-42 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's election of group I, claims 22-28, in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

5 2. Claims 29-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

10 An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Claim Rejections - 35 USC § 112

15 4. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for parathyroid hormone, does not reasonably provide enablement for a derivative thereof. The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are directed to or encompass the use of PTH "derivatives". There are no structural or functional limitations to a "derivative". The claims encompass the use of any and all conceivable compounds, including those that are structurally unrelated to PTH, because

5 every amino acid in PTH could be altered and an unlimited number of amino acids could be added thereto, for example, and the result could be called a "derivative". The specification lacks working examples of, and guidance for making, structurally unrelated compounds with the desired activity. The skilled artisan is left to unduly extensive, random, trial and error experimentation in order to obtain such useful "derivatives". Moreover, there is a lack of predictability in the art.

10 Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (u6)¹ page 1306, column 1, full paragraph 1, and Ngo (v6) page 433, full paragraph 1, and page 492, full paragraph 2. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the

15 unpredictability in the art and the quantity of experimentation needed to make or use the invention

¹Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

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based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

5 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claim 22 is indefinite over the recitation of "a parathyroid hormone" because it is unclear if parathyroid hormone or some other hormone present in or secreted from the parathyroid gland is intended. The metes and bounds of the claim(s) are not clearly set forth. It is suggested that the claims recite only "parathyroid hormone".

15 Claim 22 is indefinite because it is unclear what effect is intended by an "effective amount"; an intended use is not the same as an effect; in the absence of a recitation as to any effect, or a process step producing an effect, or an effective amount of the agent to cause an effect, it is unclear what effect can be inferred. The metes and bounds of the claim(s) are not clearly set forth. It is suggested that the claims recite "an amount of parathyroid hormone effect to increase tooth movement in said subject".

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Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Kamata (A6, cited by Applicants). Kamata teaches a method comprising administering an effective amount of a parathyroid hormone or a derivative thereof to rats (Materials and Methods, pages 412-414). The
10 rats are subjects in need of increasing tooth movement, absent evidence to the contrary.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianelly (w6) in view of Kronenberg (A1, cited by Applicants), Gardella (A7, cited by Applicants), and Sindrey (A2, cited by Applicants).

5 Gianelly teaches that it appears possible to enhance orthodontic tooth movement by the local use of parathyroid hormone (page 305, full paragraph 4). Gianelly is silent with respect to PTH(1-84) and PTH(1-34) and the purity thereof.

Kronenberg teaches human PTH(1-84) and synthetic PTH(1-34) (column 9, line 55, through column 10, line 14; Figures 1-6). Human PTH(1-84) comprises amino acids 1 to 34, as recited in claim 26.

10 Gardella teaches hPTH(1-34) (Page 15858, Experimental Procedures, column 1, full paragraph 1), which is interpreted to mean human PTH(1-34).

The term "recombinant" in claims 25, 28 is a product-by-process limitation. A process limitation is not viewed as positively limiting the PTH absent a showing that the recombinant process of making PTH imparts a novel or unexpected property to the PTH.

15 Sindrey (A2, cited by Applicants) teaches the purification of PTH (page 7, lines 8-43).

Kronenberg, Gardella, and Sindrey do not teach enhancing orthodontic tooth movement by the local use of parathyroid hormone. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to enhance orthodontic tooth movement by the local use of parathyroid hormone, as taught by Gianelly, and to modify that

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5 teaching by using purified, human PTH(1-84) or PTH(1-34), as taught by Kronenberg, Gardella, and Sindrey, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to combine these teachings because Kronenberg, Gardella, and Sindrey provide a convenient source of readily purified PTH. The invention is prima facie obvious over the prior art.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yamasaki (A5, cited by Applicants) teaches that stimulation of osteoclastic activities and the resultant bone resorption are involved in orthodontic tooth movement (Figure 7). Collins
10 (A19, cited by Applicants) teaches that although various orthodontic appliances may differ in their mode of action they all must ultimately achieve the same effect - namely, the resorption and apposition of alveolar bone to produce tooth movement in the desired direction (page 278, column 1, full paragraph 1), and suggest increasing the rate of alveolar resorption in order to increase tooth movement during orthodontic procedures (page 283, column 1, full paragraph 1).
15 It is well known that PTH increases osteoclast activity and promotes bone resorption. See Kamata (A6, cited by Applicants), page 412, full paragraph 1. The number of osteoclasts appearing during tooth movement is related to the function of PTH activity. See Kamata, page 424, full paragraph 4. Chao (A20, cited by Applicants) suggest activating alveolar bone

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resorption during orthodontic tooth movement a more rapid bone modeling and tooth movement could be achieved (Abstract, third paragraph; paragraph bridging pages 307-308).

12. No claims are allowable.

5 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

10 OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

15 
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DECEMBER 31, 2000